NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Due to time restraints, the Secretary of State's Office will no longer edit the text of proposed rules. We will continue to make numbering and labeling changes as necessary. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected **Rulemaking Action**

R4-23-604 Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. $§ 32-1904(A)(1), (3), and (4) and (B)(3)

Implementing statutes: A.R.S. §§ 32-1929, 32-1930, 32-1931, 32-1932, 32-1961, 32-1962, 32-1963, and 32-1975

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 6 A.A.R. 3116, August 18, 2000

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright
Compliance Officer

Address: Board of Pharmacy
4425 West Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, Ext. 131

Fax: (623) 934-0583

E-mail: rxcop@qwest.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

The Board's 5-year rule review in September 1997 identified Section 604 for amending. The proposed rule removes language that mimics the federal Current Good Manufacturing Practice Act and then incorporates by reference the federal Current Good Manufacturing Practice Act. The Board already enforces the federal act, so it is not necessary to have pages of rule that repeat almost verbatim the federal act. The proposed rule is updated with language required by the current Administrative Procedure Act to produce a clear, concise, and understandable document.

Subsections (A) through (G) and (I) through (L) address areas specific to Arizona that are not addressed in the federal act, including permit application, notification, drug distribution, pharmacist-in-charge, recordkeeping and retention, inspections, nonresident manufacturer, and radiopharmaceuticals. Subsection (H) incorporates the federal Current Good Manufacturing Practice Act.

The Board believes that making these rules will benefit the public health and safety by establishing clear standards for resident manufacturer permits and the manufacturing and distribution of drugs in Arizona.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The cost to the Board of Pharmacy and the Secretary of State for writing and publishing the rule will be minimal. The proposed rule will have no economic impact on drug manufacturers. The proposed rule reduces the size of the Board's rule by repealing language that mimics the federal Current Good Manufacturing Practice Act and then incorporating by reference the federal Current Good Manufacturing Practice Act. The Board already enforces the federal act, so this change will not impose anything new on manufacturers. The rule does not impose any additional costs on Arizona small business or consumers. The Board, drug manufacturers, and the public benefit from a rule that establishes clear standards for resident manufacturer permits and the manufacturing and distribution of drugs in Arizona.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright
Compliance Officer

Address: Board of Pharmacy
4425 West Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, Ext. 131

Fax: (623) 934-0583

E-mail: rxcop@qwest.net

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, April 2, 2001. An oral proceeding is scheduled for:

Date: April 2, 2001

Time: 1:00 p.m.

Location: 4425 West Olive Ave., Suite 140
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed in paragraph 4 and 9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

21 CFR 210 through 211, published April 1, 2000, and no future amendments or editions, located at A.A.C. R4-23-604(H).

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-604. ~~Manufacturers~~ Resident Drug Manufacturer

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-604. ~~Manufacturers~~ Resident Drug Manufacturer

A. Permits~~:~~

~~1. No manufacturing of a drug shall be commenced or take place before a manufacturing permit has been approved, a final inspection approved by a drug inspector and the permit is issued to the permittee.~~ A person shall not manufacture, package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical without a current Board-issued drug manufacturer permit.

B.~~2. The permittee applicant, manager and other employees at the Board's request shall furnish to the Board character references, fingerprints, education, experience and such other information as the Board may require. Records of employees shall be kept for two years and furnished to the Board on request.~~ Application: To obtain a permit to operate a drug manufacturing firm in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:

1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. Whether the owner, any officer or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
6. A copy of the drug list required by the FDA;
7. Plans or construction drawings showing facility size and security adequate for the proposed business;
8. Applicant's and manager's, if different from applicant, name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug manufacturer operation;
9. Pharmacist-in-charge's name, address, emergency telephone number, Arizona pharmacist license number, and expiration date;
10. The firm's current FDA drug manufacturer or repackager registration number and expiration date;
11. Documentation of compliance with local zoning laws;
12. For an application submitted because of ownership change, the former owner's name and business name, if different;
13. Date signed, applicant's, corporate officer's, partner's, manager's, or pharmacist-in-charge's verified signature and title, and
14. Fee specified in R4-23-205.

~~3. The owner, responsible officers and/or manager and pharmacist in charge shall appear before the Board before the permit can be issued.~~

~~4. An application shall be completed on a form furnished by the Board, showing, among other things, the pharmacist in charge as required by A.R.S. §§ 32-1929 and 32-1961. The application shall be completed and in the Board's office at least 15 days before a Board meeting before it will be considered by The Board.~~

~~5. Applications shall list drugs that are to be manufactured. Drugs may be listed by categories unless more detail is required by the Board. If other drugs are desired to be manufactured at a later date, an amendment shall be made and no distribution of such additional drugs shall be made until the Board has been notified in writing.~~

C. Before issuing a drug manufacturer permit, the Board shall:

1. Receive and approve a completed permit application;
2. Interview the applicant and manager, if different from the applicant, and the pharmacist-in-charge at a Board meeting; and
3. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

D. Notification. A drug manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, manager, or pharmacist-in-charge, including manager's or pharmacist-in-charge's telephone number.

E. Manufacturing and distribution: A drug manufacturer permittee shall manufacture and distribute a drug only:

1. To a pharmacy, drug manufacturer, and full service or nonprescription drug wholesaler currently permitted by the Board, a medical practitioner currently licensed under Title 32, or a properly permitted, registered, licensed, or certified person or firm of other jurisdictions;

2. When the drug is listed on the drug manufacturer's permit application. To receive approval to manufacture and distribute a drug not listed on a permit application, the permittee shall send a written request to amend the permit application to the Board office that includes documentation of FDA approval to manufacture the drug not listed on the original permit application. If a request to amend a permit application includes the documentation required in this subsection and if the Board or its designee determines that the amendment is in the interest of public health and safety, the Board or its designee shall approve the request to amend within 30 days of receipt; and
3. Under the supervision of an Arizona Board-licensed pharmacist as required in A.R.S. § 32-1961. Manufacturing processes that require the supervision of a pharmacist include weighing, mixing, compounding, tableting, packaging, and labeling.

E.~~6.~~ ~~Manufacturing permits are~~ A drug manufacturer permit is subject to denial, suspension, probation, or revocation ~~for violation of state or federal laws and rules pertaining to drugs, including controlled substances~~ under A.R.S. § 32-1932.

G.~~7.~~ ~~Manufacturing permittees shall comply with the registering and drug listing requirement of the Food and Drug Administration.~~ A drug manufacturer permittee shall:

1. Designate an Arizona Board-licensed pharmacist as the pharmacist-in-charge. The pharmacist-in-charge is responsible to the Board for:
   a. The operations of the drug manufacturer related to the drug manufacturing process;
   b. Communicating Board directives to the management, pharmacists, interns, and other personnel of the drug manufacturer; and
   c. The drug manufacturer's compliance with all federal and state drug laws and rules; and
2. Ensure that an Arizona Board-licensed pharmacist is present whenever a drug is manufactured, packaged, repackaged, labeled, or relabeled.

~~B~~H. ~~Finished pharmaceuticals; manufacturing practice:~~

1. ~~The criteria in R4-23-604(D)(1) through (J)(4) inclusive shall apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or holding of a drug conform to or are operated or administered in conformity with current good manufacturing practice to assure that a drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.~~
2. ~~The regulations in this part permit the use of precision automatic mechanical or electronic equipment in the production and control of drugs when adequate inspection and checking procedures are used to assure proper performance.~~ Current Good Manufacturing Practice: A drug manufacturer permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, published April 1, 2000, and no future amendments or editions, incorporated by reference and on file with the Board and the office of the Secretary of State.

~~C~~I. ~~Buildings:~~

1. ~~Buildings shall be maintained in a clean and orderly manner and shall be of suitable size, construction, and location to facilitate adequate cleaning, maintenance, and proper operations in the manufacturing, processing, packing, labeling, or holding of a drug. The building shall:~~
   a. ~~Provide adequate space for:~~
      i. ~~Orderly placement of equipment and materials to minimize any risk of mix-ups between different drugs, drug components, in-process materials, packaging materials, or labeling, and to minimize the possibility of contamination.~~
      ii. ~~The receipt, storage, and withholding from use of components pending sampling, identification, and testing prior to release by the materials approval unit for manufacturing or packaging.~~
      iii. ~~The holding of rejected components prior to disposition to preclude the possibility of their use in manufacturing or packaging procedures for which they are unsuitable.~~
      iv. ~~The storage of components, containers, packaging materials, and labeling.~~
      v. ~~Any manufacturing and processing operations performed.~~
      vi. ~~Any packaging or labeling operations.~~
      vii. ~~Storage of finished products.~~
      viii. ~~Control and production laboratory operations.~~
   b. ~~Provide adequate lighting, ventilation, and screening and, when necessary for the intended production or control purposes, provide facilities for adequate air-pressure, microbiological, dust, humidity, and temperature controls to:~~
      i. ~~Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage, or handling of another product.~~
      ii. ~~Minimize dissemination of microorganisms from one area to another.~~
      iii. ~~Provide suitable storage conditions for drug components, in-process materials, and finished drugs in conformance with stability information as derived under R4-23-604, subsection (I) paragraph (2).~~
   c. ~~Provide adequate locker facilities and hot- and cold-water washing facilities, including soap or detergent, air drier or single service towels, and clean toilet facilities near working areas.~~

~~d. Provide an adequate supply of potable water under continuous positive pressure in a plumbing system free from defects that could cause or contribute to contamination of any drug. Drains shall be of adequate size and, where connected directly to a sewer, shall be equipped with traps to prevent back-siphonage.~~
~~e. Provide suitable housing and space for the care of all laboratory animals.~~
~~f. Provide for safe and sanitary disposal of sewage, trash, and other refuse within and from the buildings and immediate premises.~~ Records: A drug manufacturer permittee shall:

1. Establish and implement written procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law;
2. Retain the records required by this Article and 21 CFR 210 through 211 for at least 2 years after distribution of a drug or 1 year after the expiration date of a drug, whichever is longer; and
3. Make the records required by this Article and 21 CFR 210 through 211 available within 48 hours for review by a Board compliance officer or other authorized officer of the law as defined in A.R.S. § 32-1901(4).

~~D~~**J.** ~~Equipment:~~

1. ~~Equipment used for the manufacture, processing, packing, labeling, holding, testing, or control of drugs shall be maintained in a clean and orderly manner and shall be of suitable design, size, construction, and location to facilitate cleaning, maintenance, and operation for its intended purpose. The Equipment shall:~~
   ~~a. Be so constructed that all surfaces that come into contact with a drug product shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.~~
   ~~b. Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not contact drug products so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.~~
   ~~c. Be constructed and installed to facilities adjustment, disassembly cleaning and maintenance to assure the reliability of control procedures, uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality, or purity of the drug or its components beyond the official or other established requirements.~~
   ~~d. Be of suitable type, size, and accuracy for any testing, measuring, mixing, weighing, or other processing or storage operations.~~ Inspections: A drug manufacturer permittee shall make the drug manufacturer's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

~~E~~**K.** ~~Personnel:~~

1. ~~The personnel responsible for directing the manufacture and control of the drug shall be adequate in number and back- ground of education, training, and experience, or combination thereof, to assure that the drug has the safety, identity, strength, quality, and purity that it purports to possess. All personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing or control operations they perform, the necessary training or experience, and adequate information concerning the reason for application of pertinent provisions of this part to their respective functions.~~
2. ~~Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drugs shall be excluded from direct contact with drug products until the condition is corrected. All employees shall be instructed to report to supervisory personnel any conditions that may have such an adverse effect on drug products.~~
3. ~~The pharmacist responsible for directing the manufacture and control of drugs shall furnish to the Board a completed fingerprint card. Fingerprint cards may also be required of other personnel at the Board's discretion.~~
4. ~~Character references shall be furnished by the pharmacist responsible for the manufacture and control of drugs and other personnel as requested by the Board. There shall be a notarized statement by such personnel concerning any and all charges of drug laws violations, past, present or pending, whether convicted or not.~~ Nonresident drug manufacturer: A nonresident drug manufacturer shall comply with the requirements of R4-23-607.

~~F.~~ ~~Production:~~

1. ~~Any and all manufacturing of drugs shall be under the supervision of an Arizona pharmacist as required in A.R.S. § 32-1961.~~
2. ~~Manufacturing processes required to be under the supervision of a pharmacist shall include, but not be limited to, such processes as weighing, mixing, compounding, tableting, packaging, and labeling.~~
3. ~~Components: All components and other materials used in the manufacture, processing, and packaging of drug products, and materials necessary for building and equipment maintenance, upon receipt shall be stored and handled in a safe, sanitary, and orderly manner. Adequate measures shall be taken to prevent mix-ups and cross-contamination affecting drugs and drug products. Components shall be withheld from use until they have been identified, sampled, and tested for conformance with established specifications and are released by a materials approval unit. Control of components shall include the following:~~
   ~~a. Each container of component shall be examined visually for damage or contamination prior to use, including examination for breakage of seals when indicated.~~

b. An adequate number of samples shall be taken from a representative number of component containers from each lot and shall be subjected to one or more tests to establish the specific identity.

c. Representative samples of components liable to contamination with filth, insect infestation, or other extraneous contaminants shall be appropriately examined.

d. Representative samples of all components intended for use as active ingredients shall be tested to determine their strength in order to assure conformance with appropriate specifications.

e. Representative samples of components liable to microbiological contamination shall be subjected to microbiological tests prior to use. Such components shall not contain microorganisms that are objectionable in view of their intended use.

f. Approved components shall be appropriately identified and retested as necessary to assure that they conform to appropriate specifications of identity, strength, quality, and purity at time of use. This requires the following:

i. Approved components shall be handled and stored to guard against contaminating or being contaminated by other drugs or components.

ii. Approved components shall be rotated in such a manner that the oldest stock is used first.

iii. Rejected components shall be identified and held to preclude their use in manufacturing or processing procedures for which they are unsuitable.

g. Appropriate records shall be maintained, including the following:

i. The identity and quantity of the component, the name of the supplier, the supplier's lot number, and the date of receipt.

ii. Examinations and tests performed and rejected components and their disposition.

iii. An individual inventory and record for each component used in each batch of drug manufactured or processed.

h. An appropriately identified reserve sample of all active ingredients consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, shall be retained for at least two years after distribution of the last drug lot incorporating the component has been completed or one year after the expiration date of this last drug lot, whichever is longer.

4. Master production and control records, batch production and control records:

a. To assure uniformity from batch to batch, a master production and control record for each drug product and each batch size of drug product shall be prepared, dated, and signed or initialed by a competent and responsible individual and shall be independently checked, reconciled, dated, and signed or initialed by a second competent and responsible individual. The master production and control record shall include:

i. The name of the product, description of the dosage form, and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of such labeling signed or initialed and dates by the person or persons responsible for approval of such labeling.

ii. The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished drug, and a statement of the total weight or measure of any dosage unit.

iii. A complete list of ingredients designated by names or codes sufficiently specific to indicate any special quality characteristic; an accurate statement of the weight or measure of each ingredient regardless of whether it appears in the finished product, except that reasonable variations may be permitted in the amount of components necessary in the preparation in dosage form provided that provisions for such variations are included in the master production and control record; an appropriate statement concerning any calculated excess of an ingredient; an appropriate statement of theoretical weight or measure at various stages of processing; and a statement of the theoretical yield.

iv. A description of the containers, closures, and packaging and finishing materials.

v. Manufacturing and control instructions, procedures, specifications, special notations, and precautions to be followed.

b. The batch production and control record shall be prepared for each batch of drug produced and shall include complete information relating to the production and control of each batch. These records shall be retained for at least two years after the batch distribution is complete or at least one year after the batch expiration date, whichever is longer. These records shall identify the specific labeling and lot or control numbers used on the batch and shall be readily available during such retention period. The batch record shall include:

i. An accurate reproduction of the appropriate master formula record checked, dated, and signed or initialed by a competent and responsible individual.

ii. A record of each significant step in the manufacturing, processing, packaging, labeling, testing, and controlling of the batch, including: dates; individual major equipment and lines employed; specific identification of each batch of components used; weights and measures of components and products used in the course of processing; in-process and laboratory control results; and identifications of the individual(s) actively performing and the individual(s) directly supervising or checking each significant step in the operation.

iii. A batch number that identifies all the production and control documents relating to the history of the batch and all lot or control numbers associated with the batch.

iv. A record of any investigation made according to R4-23-604(G)(5)(h).

5. Miscellaneous control procedures: Production and control procedures shall include all reasonable precautions, including the following, to assure that the drugs produced have the safety, identity, strength, quality, and purity they purport to possess:

a. Each significant step in the process, such as the selection, weighing, and measuring of components, the addition of ingredients during the process, weighing and measuring during various stages of the processing, and the determination of the finished yield, shall be performed by a competent and responsible individual and checked by a second competent and responsible individual; or, if such steps in the processing are controlled by precision automatic, mechanical, or electronic equipment, their proper performance is adequately checked by one or more competent and responsible individuals. The written record of the significant steps in the process shall be identified by the individual performing these tests and by the individual charged with checking these steps. Such identification shall be recorded immediately following the completion of such steps.

b. All containers, lines, and equipment used during the production of a batch of a drug shall be properly identified at all times to accurately and completely indicate their contents and, when necessary, the stage of processing of the batch.

c. To minimize contamination and prevent mix-ups, equipment, utensils, and containers shall be thoroughly and appropriately cleaned and properly stored and have previous batch identification removed or obliterated between batches or at suitable intervals in continuous production operations.

d. Appropriate precautions shall be taken to minimize microbiological and other contamination in the production of drugs purporting to be sterile or which by virtue of their intended use should be free from objectionable microorganisms.

i. Microbiological cultures and specimens to be discarded, and all other potentially infectious materials, shall be sterilized before disposal by either steam under pressure, dry heat, chemical disinfection, or in an incinerator approved by the air pollution control officer having jurisdiction.

e. Appropriate procedures shall be established to minimize the hazard of cross-contamination of any drugs while being manufactured or stored.

f. To assure the uniformity and integrity of products, there shall be adequate in-process controls, such as checking the weights and disintegration times of tablets, and the adequacy of mixing, the homogeneity of suspensions, and the clarity of solutions. In-process sampling shall be done at appropriate intervals using suitable equipment.

g. Representative samples of all dosage form drugs shall be tested to determine their conformancy with the specifications of the product before distribution.

h. Procedures shall be instituted whereby review and approval of all production and control records, including packaging and labeling, shall be made prior to the release or distribution of a batch. A thorough investigation of any unexplained discrepancy or the failure of a batch to meet any of its specifications shall be undertaken whether or not the batch has already been distributed. This investigation shall be undertaken by a competent and responsible individual and shall extend to other batches of the same drug and other drugs that may have been associated with the specific failure. A written record of the investigation shall be made and shall include the conclusions and follow -up.

i. Returned goods shall be identified as such and held. If the conditions under which returned goods have been held, stored, or shipped prior to or during their return, or the condition of the product, its container, carton, or labeling as a result of storage or shipping, cast doubt on the safety, identity, strength, quality, or purity of the drug, the returned goods shall be destroyed or subjected to adequate examination or testing to assure that the material meets all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking. If the product is neither destroyed nor returned to stock, it may be reprocessed provided the final product meets all its standards and specifications. Records of returned goods shall be maintained and shall indicate the quantity returned, date, and actual disposition of the product. If the reason for returned goods implicates associated batches, an appropriate investigation shall be made in accordance with the requirements of subparagraph (h) above.

~~G.~~ ~~Product containers and labeling:~~

1. ~~Product containers and their components: Suitable specification, test methods, cleaning procedures, and when indicated, sterilization procedures shall be used to assure that containers, closures, and other component parts of drug packages are suitable for their intended use. Product containers and their components shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug or its components beyond the official or established requirements and shall provide adequate protection against external factors that can cause deterioration or contamination of the drug.~~
2. ~~Packaging and labeling: Packaging and labeling operations shall be adequately controlled: to assure that only those drug products that have met the standards and specifications established in their master production and control records shall be distributed; to prevent mix-ups between drugs during filling, packaging, and labeling operations; to assure that correct labels and labeling are employed for the drug; and to identify the finished product with a lot or control number that permits determination of the history of the manufacturer and control of the batch. An hour, day, or shift code is appropriate as a lot or control number for drug products manufactured or processed in continuous production equipment. Packaging and labeling operations shall:~~
    a. ~~Be separated (physically or spatially) from operations on other drugs in a manner adequate to avoid mix-ups and minimize cross-contamination. Two or more packaging or labeling operations having drugs, containers, or labeling similar in appearance shall not be in process simultaneously on adjacent or nearby lines unless these operations are separated either physically or spatially.~~
    b. ~~Provide for an inspection of the facilities prior to use to assure that all drugs and previously used packaging and labeling materials have been removed.~~
    c. ~~Include the following labeling controls:~~
        i. ~~The holding of labels and package labeling upon receipt pending review and proofing against an approved final copy by a competent and responsible individual to assure that they are accurate regarding identity, content, and conformity with the approved copy before release to inventory.~~
        ii. ~~The maintenance and storage of each type of label and package labeling representing different products, strength, dosage forms, or quantity of contents in such a manner as to prevent mix-ups and provide proper identification.~~
        iii. ~~A suitable system for assuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.~~
        iv. ~~Restriction of access to labels and package labeling to authorized personnel.~~
        v. ~~Avoidance of gang printing of cut labels, cartons, or inserts when the labels, cartons, or inserts are for different products or different strengths of the same products or are of the same size and have identical or similar format and/or color schemes. If gang printing is employed, packaging and labeling operations shall provide for added control procedures. These added controls should consider sheet layout, stacking, cutting, and handling during and after printing.~~
    d. ~~Provide strict control of the package labeling issued for use with the drug. Such issue shall be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the batch production record. Said record shall identify the labeling and the quantities issued and used and shall reasonably reconcile any discrepancy between the quantity of drug finished and the quantities of labeling issued. All excess package labeling bearing lot or control numbers shall be destroyed. In event of any significant unexplained discrepancy, an investigation should be carried out according to R4-23-604(G)(5)(h).~~
    e. ~~Provide for adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all specified tests have been met.~~
3. ~~Any and all master labeling and package inserts, other printed materials and representations shall be filed with the Board before sale or distribution of the drug. All such material must comply with the federal laws as well as the Arizona laws. This is not intended to require approval by the Board before distribution.~~

~~H.~~ ~~Quality:~~

1. ~~Laboratory controls: Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, and test procedures to assure that components, in-processed drugs, and finished products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:~~
    a. ~~The establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers, and their components used in drug production and packaging and a description of the sampling and testing procedures used for them. Said samples shall be representative and adequately identified. Such records shall also provide for appropriate retesting of drug components, product containers, and their components subject to deterioration.~~
    b. ~~A reserve sample of all active ingredients as required by R4-23-604(G)(3).~~

c. The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparations. Such samples shall be adequately representative and properly identified.
d. The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drug products. Such samples shall be adequately representative and properly identified.
e. Adequate provisions for checking the identity and strength of drug products for all active ingredients and for assuring:
i. Sterility of drugs purported to be sterile and free from objectionable microorganisms for those drugs which should be so by virtue of their intended use.
ii. The absence of pyrogens for those drugs purporting to be pyrogen free.
iii. Minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances.
iv. That the drug release pattern of sustained release products is tested by laboratory methods to assure conformance to the release specifications.
f. Adequate provision for auditing the reliability, accuracy, precision, and performance of laboratory test procedures and laboratory instruments used.
g. A properly identified reserve sample of the finished product (stored in the same immediate container-closure system in which the drug is marketed) consisting of at least twice the quantity necessary to perform all the required tests, except those for sterility and determination of the absence of pyrogens, and stored under conditions consistent with product labeling shall be retained for at least two years after the drug distribution has been completed or at least one year after the drug's expiration date, whichever is longer.
h. Provision for retaining complete records of all laboratory data relating to each batch or lot of drug to which they apply. Such records shall be retained for at least two years after distribution has been completed or one year after the drug's expiration date, whichever is longer.
i. Provision that animals shall be maintained and controlled in a manner that assures suitability for their intended use. They shall be identified and appropriate records maintained to determine the history of use.
j. Provision that firms which manufacture nonpenicillin products (including certifiable antibiotic products) on the same premises or use the same equipment as that used for manufacturing penicillin products, or that operate under any circumstances that may reasonably be regarded as conducive to contamination of other drugs by penicillin, shall test such nonpenicillin products to determine whether any have become cross-contaminated by penicillin. Such products shall not be marketed if intended for use in man and the product is contaminated with an amount of penicillin equivalent to 0.03 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration, or an amount of penicillin equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use.

2. Stability: There shall be assurance of the stability of finished drug products. This stability shall be:
a. Determined by reliable, meaningful, and specific test methods.
b. Determined on products in the same container-closure systems in which they are marketed.
c. Determined on any dry drug product that is to be reconstituted at the time of dispensing (as directed in its labeling), as well as on the reconstituted product.
d. Recorded and maintained in such manner that the stability data may be utilized in establishing product expiration dates.

3. Expiration dating: To assure that drug products liable to deterioration meet appropriate standards of identity, strength, quality, and purity at the time of use, and the label of all such drugs shall have suitable expiration dates which relate to stability tests performed on the product:
a. Expiration dates appearing on the drug labeling shall be justified by readily available data from stability studies such as described in R4-23-604(I)(2).
b. Expiration dates shall be related to appropriate storage conditions stated on the labeling wherever the expiration date appears.
c. When the drug is marketed in the dry state for use in preparing a liquid product, the labeling shall bear expiration information for the reconstituted product as well as an expiration date for the dry product.

I. Distribution records:

1. Finished goods warehouse control and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and lot or control number of the drug. Records shall be retained for at least two years after the distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.
2. To assure the quality of the product, finished goods warehouse control shall also include a system whereby the oldest approved stock is distributed first whenever possible.
3. Records required for controlled substances shall be complied with.

~~4. Complaint files: Records shall be maintained of all written and oral complaints regarding each product. An investigation of each complaint shall be made in accordance with R4-23-604(G)(5)(h). The record of each investigation shall be maintained for at least two years after distribution of the drug has been completed or one year after the expiration date of the drug, whichever is longer.~~

~~J~~**L**. ~~Permit to manufacture radioactive pharmaceuticals~~ Manufacturing radiopharmaceuticals:

1. ~~Minimum requirements: The following minimum requirements, in addition to regulations pertaining to the manufacturing of other drugs, shall be met before~~ Before manufacturing a ~~radioactive pharmaceutical.~~ radiopharmaceutical, a drug manufacturer permittee shall:
   a. ~~These requirements are in addition to~~ Comply with the regulatory requirements of the Arizona Radiation Regulatory Agency~~, and~~ the U.S. Nuclear Regulatory Commission~~, and~~ the ~~federal Food and Drug Administration regulations.~~ FDA, and this Section;
   ~~a. Space: The radiopharmaceutical manufacturing or preparation area, separate and apart from other areas, shall be an undivided area of not less than 300 square feet with an additional minimum of 80 square feet for the hot lab and storage area. The area shall contain adequate sink with hot and cold water facilities.~~
   b. ~~Minimum equipment and accessory standards:~~
      ~~i. Fume hood, approved by the Arizona Radiation Regulatory Agency,~~
      ~~ii. Laminar flow hood,~~
      ~~iii. Dose calibrator,~~
      ~~iv. Refrigerator,~~
      ~~v. Electronic balance,~~
      ~~vi. Spectrophotometer,~~
      ~~vii. Drawing station,~~
      ~~viii. Radiochromatic strip scanner, well scintillation counter, scaler and multichannel analyzer,~~
      ~~ix. Microscope,~~
      ~~x. Incubator oven,~~
      ~~xi. Autoclave,~~
      ~~xii. Pyrogen oven,~~
      ~~xiii. Other equipment necessary for the radiopharmaceutical quality control for products manufactured as required by the Arizona Radiation Regulatory Agency.~~ Be or employ an authorized nuclear pharmacist as specified in R4-23-681(A);
   c. ~~Glassware:~~
      ~~i. 6 beakers 50 ml,~~
      ~~ii. 6 beakers 150 ml,~~
      ~~iii. 2 beakers 500 ml,~~
      ~~iv. 4 volumetric flasks 50 ml,~~
      ~~v. 12 volumetric flasks 100 ml,~~
      ~~vi. 4 graduated cylinders 10 ml.~~ Comply with the requirements specified in R4-23-682(F)(1), (2),(3), and (5); and
   d. ~~Supplies:~~
      ~~i. Disposable syringes 1, 3 and 5 cc,~~
      ~~ii. Multidose vials 10, 20 and 30 cc,~~
      ~~iii. Disposable alcohol swabs and gloves,~~
      ~~iv. Appropriate labels for radioactive drugs,~~
      ~~v. Other supplies necessary for drugs to be manufactured.~~ Hold a current Arizona Radiation Regulatory Agency Radioactive Materials License. A drug manufacturer permittee, who manufactures radiopharmaceuticals, that fails to maintain a current Arizona Radiation Regulatory Agency Radioactive Materials License shall be immediately suspended pending a hearing by the Board.
   ~~e.~~ ~~Reference books:~~
      ~~i. A.R.S.§ 30-651 through 30-687 pertaining to the Arizona Radiation Regulatory Agency,~~
      ~~ii. Rules of the Arizona Radiation Regulatory Agency,~~
      ~~iii. Regulations of the federal Food and Drug Administration pertaining to radioactive drugs,~~
      ~~iv. United States Pharmacopeia and National Formulary, or Remington, or United States Dispensatory, the latest edition and supplements,~~
      ~~v. American Hospital Formulary Service,~~
      ~~vi. Arizona Pharmacy Act and regulations,~~
      ~~vii. Arizona Narcotic Act,~~
      ~~viii. Radiological Health Handbook.~~
2. A drug manufacturer permittee, who manufactures a radiopharmaceutical, shall designate an authorized nuclear pharmacist as the pharmacist-in-charge. The pharmacist-in-charge is responsible to the Board for:

a. The operations of the drug manufacturer related to the manufacture and distribution of radiopharmaceuticals;
b. Communicating Board directives to the management, pharmacists, interns, and other personnel of the drug manufacturer; and
c. The drug manufacturer's compliance with all federal and state drug laws and rules.

3. An authorized nuclear pharmacist shall directly supervise all personnel performing tasks in the manufacture and distribution of radiopharmaceuticals.
4. An authorized nuclear pharmacist shall be present whenever a radiopharmaceutical is manufactured, packaged, repackaged, labeled, relabeled, or distributed.

~~K. Education and experience: In addition to the education and experience required by the Arizona Radiation Regulatory Agency, a permittee to manufacture radioactive pharmaceuticals shall present to the Board certification from an accredited college of pharmacy that the pharmacist in charge for the manufacturing of radioactive pharmaceuticals has completed courses of 90 or more clock hours of formal academic training in nuclear pharmacy and certification he has completed a minimum of three months on-the-job training under a program approved by the Board and further shall pass an examination given by the Board on good manufacturing practices.~~

~~L. Food and Drug Administration registration: A manufacturer of radioactive pharmaceuticals shall register with the federal Food and Drug Administration.~~

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-606	Amend
R4-23-607	Amend
R4-23-613	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and (2)

Implementing statutes: A.R.S. §§ 32-1904(B)(5), 32-1929, 32-1930, 32-1931, 32-1932, 32-1934, and 32-1963

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 6 A.A.R. 4759, December 22, 2000

4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Dean Wright
Compliance Officer

Address: Board of Pharmacy
4425 West Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, Ext. 131

Fax: (623) 934-0583

E-mail: rxcop@qwest.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

During the 5-year rule review in 1997, the Board staff noted that Section 606 should be revised to bring the terminology into conformity with state statute. Section 606 was originally a part of a rulemaking that included Sections 402 and 601. Because of extensive format and style changes recommended by GRRC staff, Section 606 was pulled from that rulemaking package and noticed as a separate rulemaking package. Some of the changes recommended for Section 606 ended up in a new Section 613. Section 607 is amended to include nonresident pharmacy permit requirements. The nonresident pharmacy permit requirements were inadvertently left out of Section 607 when it was amended on November 13, 2000. The proposed rule includes necessary style, format, and grammar changes to provide a clear, concise, and understandable document.

The 1999 Legislature passed H.B. 2448 (Precursor Chemical bill) requiring the Board to issue permits to anyone (resident or nonresident) who distributes precursor chemicals such as ephedrine, pseudoephedrine, and phenylpropanolamine. These chemicals are active ingredients in common over-the-counter products sold for treatment of flu, colds, and weight loss. These changes prompted the Board to require a Board-issued permit for anyone (resident or nonresident) who distributes any drug in or into Arizona. In a final rulemaking filed with the Secretary of State and effective on November 13, 2000, the Board amended Section 607 to establish the requirements for nonresident manufacturer, full service and nonprescription drug wholesaler, and nonprescription drug retailer permits. Because nonresident pharmacy permits were inadvertently left out of the previous rulemaking, this proposed rule amends Section 607 to establish the requirements for nonresident pharmacy permits.

The language in Section 606 receives numerous changes in style, format, punctuation, and grammar to comply with the statutory requirements of the Administrative Procedures Act and rules of the Secretary of State and Governor's Regulatory Review Council. Subsections (A) through (G) are amended to establish requirements related to permits, applications, notification, nonprescription drug sales, change of ownership, relocation or remodel, and changes of corporate officers. Subsections (H) through (L) are repealed.

GRRC staff recommended establishing a new Section to incorporate the procedure for closing a pharmacy in R4-23-606(L). New Section 613 includes new language establishing the procedure for discontinuing a pharmacy.

The Board believes that making these rules will benefit the public health and safety by establishing clear standards for resident and nonresident pharmacy permits and the distribution of drugs in and into Arizona.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:

Not applicable

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The rule will have a direct economic impact on nonresident pharmacies that ship drugs into Arizona. The permit fee for a resident or nonresident pharmacy is $300 biennially. In the 1999 House Bill 2448, the Arizona Legislature required that the Board issue a permit to any person who ships a precursor chemical (nonprescription drug) into the state. To accomplish this on November 13, 2000, the Board amended R4-23-601 to eliminate the exemption from registration for nonresident firms shipping prescription-only or nonprescription drugs into Arizona. This means the Board must issue a permit to any firm shipping any drug into Arizona. The cost to the Board to permit nonresident pharmacies could be substantial. These costs include identifying, contacting, and educating nonresident pharmacies regarding the new requirements, issuing and renewing permits for affected nonresident pharmacies, investigation of complaints against nonresident pharmacies, and enforcement of statutes and rules. The cost to the Board of Pharmacy and the Secretary of State for writing and publishing the rule will be minimal. The rule will have no economic impact on resident pharmacies. The rule does not impose any additional costs on Arizona small business or consumers.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright
Compliance Officer

Address: Board of Pharmacy
4425 West Olive Ave., Suite 140
Glendale, AZ 85302

Telephone: (623) 463-2727, Ext. 131

Fax: (623) 934-0583

E-mail: rxcop@qwest.net

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, April 2, 2001. An oral proceeding is scheduled for:

Date: April 2, 2001

Time: 10:00 a.m.

Location: 4425 West Olive Ave., Suite 140
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed in paragraphs 4 and 9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-606. Pharmacy Permit, Community, Hospital, and Limited Service
R4-23-607. Nonresident Permits
R4-23-613. Procedure for Discontinuing a Pharmacy

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-606. Pharmacy Permit, Community, Hospital, and Limited Service

A. ~~Pharmacy permit in general: No person may operate a pharmacy before the Board has approved the application, inspected the premises, and issued a permit.~~ Permit. A person shall not operate a pharmacy in Arizona without a current Board-issued pharmacy permit.

B. ~~Qualifications for applicants for pharmacy permit: Any person, including firm or corporation, applying for a pharmacy permit shall submit to the Board satisfactory proof that the owner, and manager has not been convicted or are not then under any charges of felony, or of an offense involving moral turpitude, or of the laws pertaining to drugs, devices and poisons. A non-pharmacist manager shall be requested to appear before the Board with the his pharmacist-in-charge before approval of the permit. Fingerprints shall be furnished at request of Board.~~ Application.

1. To obtain permit to operate a new pharmacy or change ownership, relocate, or remodel an existing pharmacy in Arizona, a person shall submit a completed application, on a form furnished by the Board, that includes:
   a. The type of pharmacy;
   b. Business name, address, mailing address, if different, telephone number, and facsimile number;
   c. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
   d. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
   e. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
   f. Whether the owner, any officer or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
   g. Whether the owner, any officer or partner is a medical practitioner;
   h. Name and telephone number of individual to contact before opening;
   i. If applying for a hospital pharmacy permit, the hospital's Department of Health Services license number, number of beds, and manager's or administrator's name;
   j. Planned opening, change of ownership, relocation, or remodel date;
   k. Plans or construction drawings showing pharmacy size and security adequate for the proposed business;

l. Documentation of compliance with local zoning laws;
m. Lease agreement and a disclosure statement indicating whether a medical practitioner receives income from the lease;
n. Pharmacist-in-charge's name and Arizona pharmacist license number;
o. For an application submitted because of ownership change, the former pharmacy's name, address, owner's name, and permit number;
p. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, or pharmacist-in-charge's verified signature and title; and
q. Fee specified in R4-23-205.

2. Before issuing a pharmacy permit, the Board shall:
a. Receive and approve a completed permit application; and
b. Receive a satisfactory compliance inspection report on the facility from a Board compliance officer.

3. Before issuing a pharmacy permit, the Board may interview the applicant and the pharmacist-in-charge, if different from the applicant, at a Board meeting.

C. ~~Pharmacy permit not issued under certain conditions: A pharmacy permit shall not be issued whereby a medical practitioner may receive compensation for his prescription orders whether directly or indirectly. This shall not include instances where sporadic prescription orders of a medical practitioner may be filled.~~ Notification. A pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, pharmacy area, ownership, address, telephone number, name of business, pharmacist-in-charge, or staff pharmacist.

D. ~~Lease may be required: A pharmacy permittee or an applicant for a pharmacy permit may be required to reveal their lease to the Board upon request to prove that a medical practitioner is not receiving more than the prevailing rent which might be considered a rebate.~~ If any nonprescription drugs are sold outside the pharmacy area when the pharmacy area is closed, the pharmacy permittee shall ensure that the business has a current Board-issued nonprescription drug permit as required in Sections R4-23-602 and R4-23-603.

E. ~~Approval of plans: The pharmacy area, waiting area, storerooms, restrooms and all partitions, doors, windows, and fixtures pertaining thereto shall be indicated on floor plans showing appropriate elevations and shall be submitted to the Board at the time the application for a new pharmacy is filed or prior to remodeling. Such plans shall be submitted prior to proceeding with new construction. Before a pharmacy permit shall be issued the plans submitted must meet the approval of the Board.~~ Change of ownership. Before any change of ownership occurs, a prospective owner shall submit the application packet described under subsection R4-23-606(B), except for changes of stock ownership of less than 30% of the voting stock of a corporation or an existing and continuing corporation that is actively traded on any securities market or over-the-counter market.

F. ~~Patent or proprietary permit required outside pharmacy area: If any drugs are sold outside the pharmacy area when the pharmacist is not in attendance, a patent or proprietary medicine permit or a general dealer's permit shall be required.~~ Before the relocation or remodel of an existing pharmacy, the pharmacy permittee shall submit the application packet described under subsection R4-23-606(B), except a fee is not required. The new or remodeled facility shall pass a final inspection by a Board compliance officer before beginning operations.

G. ~~New pharmacies: Whenever it is desired To open a new pharmacy, it shall be necessary for the ownership to apply in advance to the Board on a form prescribed and furnished by the Board. The application shall be accompanied by a biennial fee which shall be collected in accordance with the provisions of A.R.S. § 32-1931. Renewals will not be granted for a period less than 24 months. Fees are not refunded under any circumstances.~~ A pharmacy permittee shall submit the application packet described under subsection R4-23-606(B) for any change of officers in a corporation, except a fee and final inspection is not required.

~~H.~~ ~~Change of ownership: Whenever there are any changes in ownership in a pharmacy, except for changes due to death of an individual owner or of a partner, as in subsection (J) below, it shall be necessary for the new ownership to apply in advance of the change on a form prescribed and furnished by the Board, the same as for a new pharmacy, accompanied by a biennial fee as required by subsection (G) of this Section for a new pharmacy. It shall be considered a change of ownership if there is a change of stock ownership involving 30 percent or more of the voting stock of a corporation, except in an existing and continuing corporation which is actively traded on any securities market or in any over-the-counter market. Fees are not refunded under any circumstance.~~

~~I.~~ ~~Change of officers in a corporation: The Board shall be notified whenever there is a change of officers in a corporation owning a pharmacy permit, listing the new officers, and their home addresses, and additional information if required.~~

~~J.~~ ~~Change due to death of owner or partner: If there is a death of an individual owner or of a partner and it is desired to continue the operation of the pharmacy, the estate or heirs or a partnership consisting of the estate or heirs of the deceased partner and the remaining partners must file an application upon a form prescribed and furnished by the Board, for which there shall be no fee, indicating the changes which have taken place and supplying any other requested information.~~

~~K.~~ ~~Change of location: Whenever a pharmacy is to be moved to a new location it shall be necessary to apply on a form prescribed and furnished by the Board, indicating the new location and submitting plans for approval similarly to application for a new pharmacy, except there shall be no fee. The new premises shall be inspected before beginning operations.~~

~~L.~~ ~~Procedure for closing a pharmacy:~~
~~1. Ten days prior to closing, a written notice shall be sent to the Board office and to the Drug Enforcement Administration (D.E.A.). The notice shall contain, as a minimum, the following information:~~
~~a. Name, address, pharmacy permit number, and D.E.A. registration number of the pharmacy discontinuing business.~~
~~b. Name, address, pharmacy permit number (if applicable), and D.E.A. registration number of the licensee or registrant to whom the prescription drugs will be transferred.~~
~~c. The name and address of the location at which the records of the purchase and disbursement of controlled substances and prescription drugs will be kept. These records must be retained for a minimum of three years from the date of the last entry.~~
~~d. The name and address of the location at which the prescription files, patient and/or family records will be kept.~~
~~e. The proposed date of discontinuing business.~~
~~2. All drug signs and symbols must be removed from both the inside and outside of the premises.~~
~~3. All state permits and certificates of registration shall be returned to the Board office. D.E.A. registration certificates and unused D.E.A. Schedule II order forms should be returned to the D.E.A. Regional Office in Phoenix.~~
~~4. No one except The pharmacist-in-charge of the pharmacy discontinuing business shall have access to the prescription drugs until they are transferred to the new owner. When the pharmacy has been closed and the pharmacy permit has been surrendered, the prescription drugs must be removed from the premises.~~
~~5. Drugs shall be transferred in accordance with the following procedures:~~
~~a. An inventory of all controlled drugs being transferred shall be taken as of the close of business. A copy shall be used to adjust the purchaser's inventory.~~
~~b. The inventory of all Schedule II drugs shall be an accurate count. All other controlled drugs may be estimated unless quantities exceed 1,000 each, in which case an accurate count shall be made. A D.E.A. form 222 must be provided by the purchaser for Schedule II drugs.~~
~~c. The inventory shall list the name, strength, dosage form and quantity of all controlled drugs transferred.~~
~~d. Drugs to be destroyed shall be transferred in the same manner as all other drugs. The new owner shall then contact the Board office requesting an inspection for the purpose of drug destruction.~~
~~e. A copy of the inventory shall be included by the Board in the records of both the pharmacy discontinuing business and the new owner.~~
~~6. Statistical information pertaining to prescriptions, drug records, and other information pertaining to the pharmacy discontinuing business shall be furnished to the Board upon request by the individuals referred to in R4-23-606(L)(1)(c) and (d).~~

R4-23-607. Nonresident Permits

A. Permit. A person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:
1. A current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit; and
2. A current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides.

B. Application. To obtain a nonresident pharmacy, nonresident manufacturer, nonresident full service or nonprescription drug wholesale, or nonprescription drug permit, a person shall submit a completed application, on a form furnished by the Board, that includes:
1. Business name, address, mailing address, if different, telephone number, and facsimile number;
2. Owner's name, if corporation or partnership, officers or partners, including address and title, and any other trade or business names used;
3. Whether the owner, corporation, or partnership has conducted a similar business in any other jurisdiction and if so, indicate under what name and location;
4. Whether the owner, any officer or active partner has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charges, and if so, indicate charge, conviction date, jurisdiction, and location;
5. ~~Documentation of compliance with local zoning laws~~ A copy of the applicant's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides required in subsection (A)(2);
~~6~~5. For an application submitted because of ownership change, the former owner's name and business name, if different;
~~7~~6. Date signed, applicant's, corporate officer's, partner's, manager's, administrator's, pharmacist-in-charge's, or responsible person's verified signature and title, and
~~8~~7. Fee specified in R4-23-205.

C. In addition to the requirements of subsection (B), the following information is required:
1. Nonresident pharmacy.

a. The type of pharmacy;
b. Whether the owner, any officer or active partner has ever been denied a pharmacy permit in this state or any other jurisdiction, and if so, indicate where and when;
c. If applying for a hospital pharmacy permit, the number of beds, manager's or administrator's name, and a copy of the hospital's current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
d. Pharmacist-in-charge's name, Arizona pharmacist license number, and telephone number; and
e. For an application submitted because of ownership change, the former pharmacy's name, address, and permit number; and

~~1~~2. Nonresident manufacturer.
a. Whether the owner, any officer or active partner has ever been denied a drug manufacturer permit in this state or any other jurisdiction, and if so, indicate where and when;
b. A copy of the drug list required by the FDA;
~~c. Plans or construction drawings showing facility size and security adequate for the proposed business;~~
~~d~~c. Manager's or responsible person's name, address, and emergency telephone number; and
~~e~~d. The firm's current FDA drug manufacturer or repackager registration number and expiration date; and

~~2~~3. Nonresident full service or nonprescription drug wholesaler.
a. The type of drug wholesale permit;
b. Whether the owner, any officer or active partner has ever been denied a drug wholesale permit in this state or any other jurisdiction, and if so, indicate where and when;
c. The type of drugs, nonprescription, prescription-only, controlled substances, human, or veterinary, the applicant will distribute;
~~d. Plans or construction drawings showing facility size and security adequate for the proposed business;~~
~~e~~d. Manager's or responsible person's name, address, emergency telephone number, and resume indicating educational or experiential qualifications related to drug wholesale operation; and

~~3~~4. Nonresident nonprescription drug retailer.
a. Whether applying for Category I or Category II permit;
b. Date business started or planned opening date; and
c. Type of business, such as convenience, drug, grocery, or health food store, swap-meet vendor, or vending machine.

D. Notification.
1. Nonresident pharmacy. A nonresident pharmacy permittee shall notify the Board of changes involving the type of pharmacy operated, ownership, address, telephone number, name of business, or pharmacist-in-charge.
~~1~~2. Nonresident manufacturer. A nonresident manufacturer permittee shall notify the Board of changes involving listed drugs, ownership, address, telephone number, name of business, or manager including manager's telephone number.
~~2~~3. Nonresident drug wholesaler. A nonresident full service or nonprescription drug wholesale permittee shall notify the Board of changes involving the type of drugs sold or distributed, ownership, address, telephone number, name of business, or manager including manager's telephone number.
~~3~~4. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall notify the Board of changes involving permit category, ownership, address, telephone number, name of business, or manager including manager's telephone number.

E. Drug Sales.
1. Nonresident pharmacy. A nonresident pharmacy permittee shall not:
a. Sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except:
i. A pharmacy, drug manufacturer, or full service drug wholesaler currently permitted by the Board;
ii. A medical practitioner currently licensed under A.R.S. Title 32; or
iii. An Arizona resident upon receipt of a valid prescription order for the resident; and
b. Sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except:
i. A pharmacy, drug manufacturer, full service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board;
ii. A medical practitioner currently licensed under A.R.S. Title 32; or
iii. An Arizona resident either upon receipt of a valid prescription order for the resident or in the original container packaged and labeled by the manufacturer.

~~1~~2. Nonresident manufacturer. A nonresident manufacturer permittee shall not:
a. Sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except, a pharmacy, drug manufacturer, or full service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32; and

b. Sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32.

~~2~~3. Nonresident full service drug wholesaler. A nonresident full service drug wholesale permittee shall not:
a. Sell, distribute, give away, or dispose of, any narcotic or other controlled substance or prescription-only drug or device, to anyone in Arizona except a pharmacy, drug manufacturer, or full service drug wholesaler currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32; and
b. Sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32.

~~3~~4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except, a pharmacy, drug manufacturer, full service or nonprescription drug wholesaler, or nonprescription drug retailer currently permitted by the Board or a medical practitioner currently licensed under A.R.S. Title 32.

~~4~~5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
a. Sell, distribute, give away, or dispose of, a nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona except in the original container packaged and labeled by the manufacturer;
b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical; and
c. Sell, distribute, give away, or dispose of, any drug, precursor chemical, or regulated chemical to anyone in Arizona that exceeds its expiration date, is contaminated or deteriorated from excessive heat, cold, sunlight, moisture, or other factors, or does not comply with federal law.

F. A nonresident pharmacy permittee shall ensure that the pharmacist-in-charge has a current Arizona Board-issued pharmacist license.

~~F~~G. When selling or distributing any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona, a nonresident pharmacy, nonresident manufacturer, nonresident full service or nonprescription drug wholesale, or nonprescription drug permittee shall comply with federal law, the permittee's resident state drug law, and this Section.

R4-23-613. Procedure for Discontinuing a Pharmacy

A. A pharmacy permittee or pharmacist-in-charge shall provide written notice to the Board and the Drug Enforcement Administration (D.E.A.) at least 10 days before discontinuing operation of the pharmacy. The notice shall contain the following information:
1. Name, address, pharmacy permit number, and D.E.A. registration number of the pharmacy discontinuing business;
2. Name, address, pharmacy permit number (if applicable), and D.E.A. registration number of the licensee, permittee, or registrant to whom the prescription-only drugs and controlled substances will be sold or transferred;
3. Name and address of the location where the discontinuing pharmacy's records of purchase and disbursement of controlled substances and prescription-only drugs will be kept. These records shall be kept for a minimum of three years from the last transaction date.
4. Name and address of the location where the discontinuing pharmacy's prescription files and patient profiles will be kept. These records shall be kept for a minimum of three years from the date the last original or refill prescription was dispensed; and
5. The proposed date of discontinuing business operations.

B. The pharmacy permittee shall ensure that all pharmacy signs and symbols are removed from both the inside and outside of the premises.

C. The pharmacy permittee or pharmacist-in-charge shall ensure that all state permits and certificates of registration are returned to the Board office and D.E.A. registration certificates and unused D.E.A. Schedule II order forms are returned to the D.E.A. Regional Office in Phoenix.

D. The pharmacist-in-charge of the pharmacy discontinuing business shall ensure that:
1. Only a pharmacist has access to the prescription-only drugs and controlled substances until they are transferred to the licensee, permittee, or registrant listed in subsection (A)(2);
2. All prescription-only drugs and controlled substances are removed from the premises on or before the date the pharmacy is discontinued; and
3. All controlled substances are transferred as follows:
a. Take an inventory of all controlled substances that are transferred using the procedures in R4-23-1003;
b. Include a copy of the inventory with the controlled substances that are transferred;
c. Keep the original of the inventory with the discontinued pharmacy's records of drug purchase and disbursement for a minimum of three years from the date the pharmacy is discontinued;

d. Use a D.E.A. form 222 to transfer any Schedule II controlled substances; and
e. Transfer controlled substances that need destruction in the same manner as all other controlled substances.

E. Upon receipt of outdated or damaged controlled substances from a discontinued pharmacy, the licensee, permittee, or registrant described in subsection (A)(2) shall contact a D.E.A. registered reverse distributor for proper destruction of outdated or damaged controlled substances. If there are controlled substances a reverse distributor will not accept, the licensee, permittee, or registrant shall then contact the Board office requesting an inspection for the purpose of drug destruction.

F. During the three year record retention period, the person described in subsection (A)(3) or (4) shall provide to the Board upon its request a discontinued pharmacy's records of the purchase and disbursement of controlled substances and prescription-only drugs, prescription files, and patient profiles.

NOTICE OF PROPOSED RULEMAKING

TITLE 15. REVENUE

CHAPTER 2. DEPARTMENT OF REVENUE
INCOME AND WITHHOLDING TAX SECTION
SUBCHAPTER A. GENERAL AND ADMINISTRATIVE

PREAMBLE

1. Sections Affected **Rulemaking Action**

R15-2A-102	Repeal
R15-2A-103	Amend
R15-2A-104	Amend
R15-2A-201	Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 42-1005

Implementing statutes: A.R.S. §§ 1-218, 43-301, 43-304, 43-308, 43-325, 43-328, 43-933, 43-1126, and 43-1241

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 6 A.A.R. 1917, May 26, 2000

Notice of Recodification: 6 A.A.R. 2308, June 23, 2000

Notice of Rulemaking Docket Opening: 6 A.A.R. 4047, October 20, 2000

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Jim Bilski
Tax Analyst

Address: Tax Research & Analysis Section
Arizona Department of Revenue
1600 West Monroe
Phoenix, AZ 85007

Telephone: (602) 542-4672

Fax: (602) 542-4680

E-mail: BilskiJ@revenue.state.az.us

5. An explanation of the rule, including the agency's reasons for initiating the rule:

R15-2A-102 is being repealed because it is inconsistent with the statutes (A.R.S. §§ 43-301 and 43-304) and merely repeats the items of income included in Internal Revenue Code § 61.

R15-2A-103 is being amended to incorporate the provisions of A.R.S. § 1-218(E), which relates to designated delivery services under the Internal Revenue Code. This is also amended to include 2 additional exceptions to the normal filing deadline and to comply with current rulewriting guidelines.

R15-2A-104 is being amended to specify the procedure for requesting relief from interest and penalties for failing to file timely an Arizona individual income tax return or perform any other act required by A.R.S. Title 43.

R15-2A-201 is being repealed because it is inconsistent with the underlying statute and includes a reference to an example that is not included in the rule.

6. Reference to any study that the agency relied on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

It is expected that the benefits of the rules will be greater than the costs. Amending the rules will benefit the public by making the rules consistent with current statute and removing language that is obsolete or that is repetitive of statute. Further, by amending the rules to conform to current rulemaking guidelines, the rules will be clearer and easier to understand. Certain taxpayers and the Department are expected to incur minimal costs associated with the written request required under R15-2A-104. The Department, the Governor's Regulatory Review Council, and the Secretary of State's Office will incur the costs associated with the rulemaking process.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Jim Bilski Tax Analyst
Address:	Tax Research & Analysis Section Arizona Department of Revenue 1600 West Monroe Phoenix, AZ 85007
Telephone:	(602) 542-4672
Fax:	(602) 542-4680
E-mail:	BilskiJ@revenue.state.az.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

The Department has not scheduled any oral proceedings. Written comments on the proposed rules or preliminary economic, small business, and consumer impact statements may be submitted to the person listed above. Pursuant to A.R.S. § 41-1023(C), the Department will schedule oral proceedings if 1 or more individuals file written requests for oral proceedings within 30 days after the publication of this Notice.

A person may submit written comments regarding the proposed rulemaking action by submitting the comments no later than 5:00 p.m., March 26, 2001, to the person listed in paragraphs 4 and 9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 15. REVENUE

CHAPTER 2. DEPARTMENT OF REVENUE
INCOME AND WITHHOLDING TAX SECTION
SUBCHAPTER A. GENERAL AND ADMINISTRATIVE

ARTICLE 1. DEFINITIONS AND GENERAL PROVISIONS

R15-2A-102. ~~Gross Income Defined for Purposes of Determination to File~~ Repealed
R15-2A-103. Time for Filing Returns
R15-2A-104. Returns Filed by Persons Outside the United States

ARTICLE 2. GENERAL ACCOUNTING PROVISIONS

R15-2A-201. ~~Application to File Return for Short Period Income~~ Repealed

ARTICLE 1. DEFINITIONS AND GENERAL PROVISIONS

R15-2A-102. ~~Gross Income Defined for Purposes of Determination to File~~ Repealed

~~**A.** "Gross income" for the purposes of this Article shall be the gross income as defined in the Internal Revenue Code, Section 61.~~

~~**B.** Fifteen of the more common types of "gross income" are enumerated by Code Section 61 and are:~~

~~1. Compensation for services including fees, commissions, and similar items~~
~~2. Gross income from business~~
~~3. Gains from dealing in property~~
~~4. Interest~~
~~5. Rents~~
~~6. Royalties~~
~~7. Dividends~~
~~8. Alimony and separate maintenance payments~~
~~9. Annuities~~
~~10. Income from life insurance and endowment contracts~~
~~11. Pensions~~
~~12. Income from discharge of debt~~
~~13. Partner's share of partnership income~~
~~14. Income "in respect of a decedent" and~~
~~15. Income from an interest in an estate or trust.~~

~~**C.** Although nearly ever conceivable item of income may seem to fall within the above definitions, income items should nevertheless be checked against the specific exclusions in Code Section 101-123 of the Internal Revenue Code.~~

R15-2A-103. Time for Filing Returns

A. Generally, a taxpayer shall file an income tax return ~~returns of income must be filed~~ on or before the 15th day of the 4th full calendar month following the close of the taxable year. This ~~rule~~ requirement is subject to ~~several~~ the following exceptions ~~in which the time for filing is as follows~~:

1. ~~In the case of a~~ The final return of a decedent for a fractional part of a year ~~the return~~ shall be filed on or before the 15th day of the 4th month following the close of the 12-month period ~~which~~ that began with the 1st day of ~~such fractional part of~~ the taxable year in which the decedent died.
2. ~~In the case of any return for a fractional part of a year, the~~ The Department may ~~upon a showing by the taxpayer of unusual circumstances,~~ prescribe a later time for ~~the~~ filing ~~of the~~ a return for a fractional part of a year upon a showing by the taxpayer of unusual circumstances.
3. ~~In the case of a~~ A corporation ~~going into liquidation~~ that has liquidated during any taxable year ~~after completion of such liquidation, the corporation~~ may prepare a return for that year covering the income of the corporation for the part of the year during which ~~it~~ the corporation was engaged in business and may immediately file ~~such~~ the return with the Department.
4. Under A.R.S. § 43-1126, a corporation taxable as an S corporation under the Internal Revenue Code shall file its income tax return on or before the 15th day of the 3rd month following the close of the taxable year.
5. Under A.R.S. § 43-1241, an organization, otherwise exempt under A.R.S. § 43-1201, having unrelated business income shall file its income tax return on or before the 15th day of the 5th month following the close of the taxable year.

B. The due date is the date on or before which a return is required to be filed ~~in accordance with the provisions of the Act and the regulations prescribed thereunder~~ under A.R.S. Title 43 or the last day of the period covered by ~~an~~ a filing extension ~~of time~~ granted by ~~this~~ the Department. When the due date falls on Saturday, Sunday, or a legal holiday, the due date for filing ~~returns will be~~ the return is the business day following ~~such~~ the Saturday, Sunday, or legal holiday. ~~If placed in the mails, the returns should be posted in ample time under ordinary handling of the mails to reach the office of the Department on or before the date on which the return is required to be filed. If a return is made and placed in the mails properly addressed and postage paid on or before the due date, a penalty will not be attached should the return not actually be received by such office until subsequent to that date.~~

C. A return that is placed in the United States mail, properly addressed with postage paid, shall be deemed to be filed on the date of the postmark stamped on the cover in which the return is mailed. For purposes of this subsection, the terms "United States mail" and "postmark" have the same meaning as prescribed in A.R.S. § 1-218(E).

R15-2A-104. Returns Filed by Persons Outside the United States

A. If by reason of being outside the United States a taxpayer is unable to file an Arizona individual income tax return or perform any other act ~~as~~ required by A.R.S. Title 43, the taxpayer ~~he~~ may ~~by written request to the Income Tax Audit Section explain the circumstances and~~ request that the Department disregard the period in which he or she was unable to comply ~~be disregarded~~. A taxpayer requesting relief shall do the following:

1. The taxpayer shall file a written request with the Department as soon as possible after returning to the United States.
2. The taxpayer's request shall explain the reasons why the taxpayer was unable to file the return or perform the required act.
3. The taxpayer's request shall indicate the time period in which the taxpayer was unable to file the return or perform the required act.
4. If the request relates to the failure to file a return, the taxpayer shall include the return and any applicable tax payment with the request.
5. The taxpayer shall mail the request to the Arizona Department of Revenue, Out of Country Waiver, 1600 West Monroe, Phoenix, Arizona 85007.

B. The Department shall consider a request filed within 30 days after a taxpayer returns to the United States to be filed as soon as possible. The Department may extend the request period if there are circumstances that prevent the taxpayer from filing the request within 30 days after the taxpayer returns to the United States. ~~The written explanation for the taxpayer being unable to file his return shall be submitted to the Department as soon as possible after his return to the United States.~~

C. A taxpayer that is unable to submit the return referenced in subsection (A)(4), may request an extension to file provided all of the other requirements in subsection (A), including payment of the tax due, are met. The taxpayer will be required to provide documentation of the ongoing reasons for the taxpayer's inability to file the return.

D. If the Department determines that ~~the causes are such that~~ it was impossible or impracticable for the taxpayer to ~~otherwise~~ timely file a ~~his~~ return or perform the required act, the Department shall relieve the taxpayer ~~will be relieved~~ from the interest and penalties that would have accrued from the ~~his~~ failure to file a timely return or perform the required act.

ARTICLE 2. GENERAL ACCOUNTING PROVISIONS

R15-2A-201. ~~Application to File Return for Short Period Income~~ Repealed

~~A taxpayer desiring the benefit of Section 43-933 must file an application for it. The application for the benefits of Section 43-933 must be filed not later than the time prescribed for filing the taxpayer's return for the 1st taxable year which ends on or after the last day of December or the 12th month after the beginning of the short period. In this case, the taxpayer must file his application not later than January 15, the time prescribed for filing the return for his fiscal year ending September 30. However, if he obtains an extension of time for filing the return for such fiscal year, he may file his application during the period of such extension. If the Department determines that the taxpayer has established the amount of the net income for the 12-month period, any excess of the tax paid for the short period over the tax computed under Section 43-933 will be credited or refunded to the taxpayer in the same manner as in the case of an overpayment.~~

NOTICE OF PROPOSED RULEMAKING

TITLE 17. TRANSPORTATION

CHAPTER 3. DEPARTMENT OF TRANSPORTATION - HIGHWAYS DIVISION

PREAMBLE

1. Sections Affected **Rulemaking Action**

R17-3-402 Repeal

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 28-366

Implementing statute: A.R.S. § 28-7045

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 921, February 16, 2001

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Wendy S. LeStarge
Rules Analyst

Address: Arizona Department of Transportation
Administrative Rules Unit, Mail Drop 507M
3737 North Seventh Street, Suite 160
Phoenix, Arizona 85014-5017

Telephone: (602) 712-6007

Fax: (602) 241-1624

E-mail: wlestarge@dot.state.az.us

5. An explanation of the rule, including the agency's reasons for initiating the rule:

This rulemaking deals with weight restrictions on State Highway 377. The agency seeks to repeal this rule since the weight restrictions are no longer necessary due to reengineering of the state highway. This rulemaking arises from proposed agency action in the 5-year review report approved by the Governor's Regulatory Review Council on May 2, 2000 (F-00-0402).

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The Department claims exemption under A.R.S. § 41-1055(D). The only foreseen economic impact of repealing R17-3-402 is clerical costs involved in formal rulemaking. Repeal of these unnecessary rules decreases agency monitoring and enforcing burdens required of effective administrative rules.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Wendy S. LeStarge
Rules Analyst

Address: Arizona Department of Transportation
Administrative Rules Unit, Mail Drop 507M
3737 North Seventh Street, Suite 160
Phoenix, Arizona 85014-5017

Telephone: (602) 712-6007

Fax: (602) 241-1624

E-mail: wlestarge@dot.state.az.us

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

No oral proceeding is scheduled for this rulemaking. Written, faxed, e-mail comments, or requests for an oral proceeding may be made by contacting the officer listed in #4 between 8:00 a.m. and 4:30 p.m., Monday through Friday. If no oral proceeding is requested, the public comment period shall continue for 30 days from this notice's publication date. This rulemaking's public record will close at 4:30 p.m. on March 24, 2001.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

12. Incorporations by reference and their location in the rules:

Not applicable

13. The full text of the rules follows:

TITLE 17. TRANSPORTATION

CHAPTER 3. DEPARTMENT OF TRANSPORTATION - HIGHWAYS DIVISION

ARTICLE 4. HIGHWAY LIMITATIONS (WEIGHT RESTRICTIONS AND TRAFFIC CONTROLS)

R17-3-402. Weight restrictions on State Highway 377 Repealed

R17-3-402. ~~Weight restrictions on State Highway 377~~ Repealed

~~A maximum gross weight restriction of 40,000 pounds (20 tons) in total is imposed on that portion of State Highway 377 between Holbrook and Heber, described as follows:~~

~~1. Beginning on State Highway 377 from Milepost 0.00 at its intersection with State Highway 277 to Milepost 33.83 at its intersection with State Highway 77.~~

NOTICE OF PROPOSED RULEMAKING

TITLE 19. ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 3. ARIZONA STATE LOTTERY COMMISSION

PREAMBLE

1. Sections Affected **Rulemaking Action**

Article 2
R19-3-208 New Section

2. The specific authority for rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 5-504(B)

Implementing statute: A.R.S. § 5-512(I)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 7 A.A.R. 922, February 16, 2001

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Mr. Geoffrey Gonsher
Executive Director

Address: 4740 East University
Phoenix, AZ 85034

Telephone: (602) 921-4514

Fax: (602) 921-4488

5. An explanation of the rule, including the agency's reason for initiating the rule:

Retailer rules, A.A.C. R19-3-201 through R19-3-207, are required by A.R.S. § 5-504 and prescribe the requirements and procedures for Arizona retailer businesses to obtain a license to sell Lottery game products, display promotional materials, requirements for the sale and payment of instant games and on-line games, and retailer conduct. The rules establish procedures for revocation, suspension or renewal of retailer licenses, hearing procedures and Lottery-conducted compliance investigations. This amendment, which adds an additional Section, will establish penalties required by A.R.S. §5-512(I), as amended by Laws 2000, Ch. 326, § 3, Forty-fourth Legislature, Second Regular Session, for the sale of a Lottery ticket to an underage person or to a person using a public assistance voucher or an electronic benefits transfer card to purchase the ticket.

6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

A. The Arizona State Lottery.

Costs to the Lottery for this Article are included in the agency's appropriated budget. Relevant retailer-related costs include background investigations for licensing and statutory compliance, delivery of tickets, supplies and point-of-sale promotional items, installation of telephone lines for the on-line terminal and monthly communication fees for each retailer selling on-line games, and administrative costs for collecting sales revenues and providing customer service to retailers. Cost of a licensing investigation, which includes an Americans with Disabilities Act (ADA) on-site inspection, is approximately $200 per location. There are additional costs of compliance investigations performed by the Lottery's investigators and administrative review by the Office of Administrative Hearings if a retailer files an appeal. Initial telecommunication line installation for an on-line retailer terminal is approximately $550 and the average monthly line charge is $61. The Lottery has approximately 2500 on-line retailers. The Lottery paid $1.8 million in telecommunication line-charges in fiscal year 2000.

B. Political Subdivisions.

Political subdivisions of this state are not directly affected by the Retailer rules.

C. Businesses Directly Affected by the Rulemaking.

Businesses affected by this rule are those retailers that choose to apply for a Lottery license to sell Lottery game products to the public. The rule provides for licensing requirements, retailer conduct in selling and redeeming Lottery tickets, and compensation paid to retailers for Lottery services. The Lottery paid retailers over $16 million in commissions in fiscal year 2000. The new Section provides for penalties for a licensed retailer who violates A.R.S. § 5-515 or A.R.S. § 5-515.01. Only those retailers who sell a ticket to an underage person or to a person who uses either a public assistance voucher or an electronic benefits transfer card to purchase the ticket are affected by the new Section.

D. Private and Public Employment.

Private and public employees are not directly affected by this rule.

E. Consumers and the Public.

There are no costs to the public associated with the amendment of this rule.

F. State Revenues.

License fees and revenue generated by the sale of Lottery game tickets are distributed to those programs funded with Lottery monies. The Lottery collected $10,000 in retailer license fees in fiscal year 2000. Transfers to state of Arizona funds were in excess of $78 million. The Lottery experiences minimal rule violations and, therefore, does not expect the collection of civil penalties to have a major impact on state revenues.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Mr. Geoffrey Gonsher Executive Director
Address:	4740 East University Phoenix, AZ 85034
Telephone:	(602) 921-4514
Fax:	(602) 921-4488

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Date: March 27, 2001

Time: 10:00 a.m.

Location: Arizona State Lottery
4740 East University
Phoenix, AZ 85034

Nature: Oral Proceeding (Close of the record is 5:00 p.m., M.S.T., Monday, March 26, 2001, for written comments and at the end of the oral proceeding for verbal comments.)

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporation by reference and their location in the rules:

Not applicable

13. The full text of the rules follows:

TITLE 19: ALCOHOL, HORSE AND DOG RACING, LOTTERY, AND GAMING

CHAPTER 3: ARIZONA STATE LOTTERY COMMISSION

ARTICLE 2. RETAILERS

R19-3-208. Penalties

ARTICLE 2. RETAILERS

R19-3-208. Penalties

A. A retailer may be assessed a civil penalty for any of the following reasons:
1. Until June 1, 2003, offering to sell or selling a lottery ticket or share to any person who is under 18 years of age.
2. Beginning on June 1, 2003, offering to sell or selling a lottery ticket or share to any person who is under 21 years of age.
3. Selling a lottery ticket or share to a person who uses either a public assistance voucher issued by any public entity or an electronic benefits transfer card issued by the Arizona Department of Economic Security to purchase the ticket or share.
4. Selling a lottery ticket or share during the same transaction in which a person uses either a public assistance voucher issued by any public entity or an electronic benefits transfer card issued by the Arizona Department of Economic Security.

B. The Director may on the Director's own motion, and shall on the written complaint of any person, investigate an act of the retailer listed in subsection (A). The Director may give notice of his imposition of a civil penalty if the retailer is found to have committed an act listed in subsection (A). The civil penalty for an act listed in subsection (A) shall be:
1. A civil penalty in an amount up to $300 for the first violation;
2. A civil penalty in an amount over $300 and up to $500 for the second violation within a 12-month period; and
3. A civil penalty in an amount over $500 and up to $1,000 for the third violation within a 12-month period.

C. A penalty assessed by the Director is due to the Lottery on the 31st day after receipt of the notice of imposition of the civil penalty, if the notice is not appealed.

D. Procedures for hearings. A retailer may request a hearing regarding imposition of a civil penalty. The hearing shall be conducted in accordance with A.R.S. Title 41, Chapter 6, Article 10.

E. A decision of the Director accepting, modifying or rejecting the recommended decision of the Administrative Law Judge is a final decision that is subject to judicial review under A.R.S. Title 12, Chapter 7, Article 6.
1. If the decision is not appealed, the civil penalty is due on the 36th day after receipt of the Director's decision.
2. If the decision is appealed and the imposition of the civil penalty is affirmed on appeal, the civil penalty is due on the 36th day after the decision is dated.
3. If the decision is further appealed, the imposition of the civil penalty is due on the 36th day after the decision is affirmed.
4. The Lottery will receive interest at the rate provided in A.R.S. § 44-1201 from the date of entry of the final judgment assessing a civil penalty until satisfaction of the judgment.